EXHIBIT 2

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Milton and Danae Reynolds

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

MILTON AND DANAE REYNOLDS, Plaintiffs, v. EZRICARE, LLC; EZRIRX, LLC; GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED; ARU PHARMA, INC.; AMAZON.COM, INC.; AND "DOE" AMAZON DELIVERY SERVICE PARTNER, Defendants.	Case No: 23CV028265 **COMPLAINT FOR DAMAGES** (1) Strict Liability – Manufacturing Defect (2) Strict Liability – Design Defect (3) Strict Liability – Failure to Warn (4) Negligence & Gross Negligence (5) Negligent Failure to Warn (6) Negligent Failure to Recall (7) Negligence Per Se (8) Breach of Express Warranty (9) Breach of Implied Warranty (10) Fraud (11) Loss of Consortium **DEMAND FOR JURY TRIAL**

Plaintiff Milton Reynolds files this Complaint having suffered blindness in his right eye from using contaminated EzriCare Artificial Tears. Plaintiff Danae Reynolds files this complaint having suffered loss of consortium because of Mr. Reynold's injuries. On information and belief, the Reynolds allege as follows:

PARTIES

Plaintiffs Milton Reynolds and Danae Reynolds are a married couple. They are residents of San Leandro, California. At all times relevant to this lawsuit, Mr. and Mrs. Reynolds were residents

of San Leandro, California. The injury for which Mr. and Mrs. Reynolds are suing occurred in San Leandro, California.

Defendant Amazon.com, Inc. ("Amazon") is incorporated under the laws of Delaware and maintains its principal place of business in Washington. Amazon markets, sells, and distributes products worldwide, including in California. Amazon does business in California, both online and through its offices and operations in California. Amazon purposely directed its activities to California and sold, distributed, advertised, and/or marketed the product that caused injury giving rise to this lawsuit. Amazon's contacts with California are substantial and sufficient that the company should reasonably expect to be brought into court in California. Amazon may be served through its registered agent, Corporation Service Company, at 300 Deschutes Way SW, Ste. 208 M; C-CSC1, Tumwater, WA 98501.

Defendant "Doe" is a currently unidentified Amazon Delivery Service Partner ("DSP") added pursuant to California Code of Civil Procedure 474. On information and belief, Defendant Doe is an independent, California company responsible for distributing packages "the last mile" from a California-based facility to California customers when those customers place orders from Defendant Amazon.[1] A search for California-based DSP jobs on ZipRecruiter returns 465 available positions at various DSP companies.[2] On information and belief, Defendant Doe was responsible for distributing and delivering the product that caused the injury in this lawsuit. Thus, Defendant Doe purposely directed its activities to California. Doe's contacts with California are substantial and sufficient that the company should reasonably expect to be brought into court in California.

Defendant Aru Pharma, Inc. ("Aru Pharma") is incorporated under the laws of the State of New York, and its principal place of business is located at 925 Protano Lane, Mamaroneck, NY

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[1] *See Rimson v. Amazon Logistics, Inc.* (W.D. Mo., Jan. 25, 2023, No. 4:21-00553-CV-RK) 2023 WL 405336, at *1 (In its motion for summary judgment, Defendant Venus' statement of uncontroverted material facts explains that Amazon hires third-party companies, known as Delivery Service Partners ('DSP'), to deliver Amazon packages. Amazon has delivery stations, called DMCs, where the packages go for the last mile before they arrive to the customer."; *see also* Amazon, *Own Your Success: Start Your Own Business and Become an Amazon Delivery Service Partner, Delivering Smiles Across Your Community*, accessed Feb. 16, 2023, https://m.media-amazon.com/images/G/01/DSP2022/assets/desktop/DSP_Brochure_English_V4.pdf.

[2] ZipRecruiter, Amazon Delivery Partner Jobs (in California), accessed Feb. 16, 2023, https://www.ziprecruiter.com/Jobs/Amazon-Delivery-Partner/--in-California.

10543. Aru Pharma is in the business of manufacturing, designing, importing, supplying, packaging, labeling, distributing, marketing, and selling the product that caused injury in this case in California. Thus, Aru Pharma purposely directed its activities to California. Aru Pharma's contacts with California are substantial and sufficient that the company should reasonably expect to be brought into court in California. Aru Pharma may be served with process via Kuppusamy Arumugam at its principal place of business 925 Protano Lane, Mamaroneck, NY 10543 (or alternatively on Jayakumar Arumugam at 7 Wingate Pl., Yonkers, NY 10705).

Defendant EzriCare, LLC ("EzriCare") is a limited liability company organized under the laws of the State of New Jersey. EzriCare's principal place of business is located at 1525 Prospect St., Ste. 204, Lakewood, NJ 08701. EzriCare is a citizen of the State of New Jersey. EzriCare is in the business of manufacturing, designing, importing, labeling, packaging, supplying, distributing, marketing, and selling the product that caused the injury in this lawsuit throughout the United States, including in California. Thus, EzriCare purposely directed its activities to California. EzriCare's contacts with California are substantial and sufficient that the company should reasonably expect to be brought into court in California. EzriCare may be served through its registered agent, Ezriel Green, at 1525 Prospect St., Ste. 204, Lakewood, NJ 08701.

Defendant EzriRx, LLC ("EzriRx") is organized under the laws of the State of Delaware. EzriRx's principal place of business is located at 1525 Prospect St., Ste. 203, Lakewood, NJ 08701 or 2360 Rt. 9, Suite 3, #171, Toms River, NJ 08755. EzriRx is in the business of manufacturing, designing, importing, supplying, packaging, labeling, distributing, marketing, and selling the product that caused injury in this lawsuit throughout the United States, including in California. Thus, EzriRx purposely directed its activities to California. EzriRx's contacts with California are substantial and sufficient that the company should reasonably expect to be brought into court in California. EzriRx may be served through its registered agent Registered Agent Solutions, Inc., 838 Walker Road, Suite 21-2, Dover, Delaware 19904.

Defendant Global Pharma Healthcare Private Limited ("Global Pharma") is a corporation organized and existing under the laws of the Country of India. Global Pharma's principal place of business located at No. 2A, 3rd F, 4th Street, Ganga Nagar, Chennai - 600 024, Tamilnadu, India.

Global Pharma is in the business of manufacturing, designing, importing, marketing, advertising, packing, labeling, distributing, and selling the product that caused the injury that is the subject of this lawsuit. As can be seen on its website, Global Pharma purposely directed its activities to the U.S. market, including California.[3] EzriRx's contacts with California are substantial and sufficient that the company should reasonably expect to be brought into court in California. Global Pharma can be served at its offices and through its officers via the Hague Service Convention.

Each Defendant received direct financial benefit from its activities and the sale of the product at issue in this lawsuit. Each Defendant was integral to the business enterprise such that Defendants' conduct was a necessary factor in bringing the product to the customer market. Each Defendant had control over or a substantial ability to influence the distribution and marketing process.

JURISDICTION AND VENUE

This Court has jurisdiction over the subject matter of this action as a tort committed upon Alameda County residents and pursuant to Article VI, Section 10 of the California Constitution because this case is not given by statute to other trial courts. Additionally, the amount in controversy exceeds the amount for unlimited civil jurisdiction in this Court.

This court has jurisdiction over each Defendant because, on information and belief, each Defendant conducts business in this state, has purposely availed itself of the laws of this state, and purposely directed its business to the state. Moreover, the injuries that are the subject of this lawsuit were caused by a product that was sold, distributed, delivered, used, and caused injury to the Plaintiffs in Alameda County. Thus, the controversy arises out of Defendants contacts with the state and the forum.

Venue lies in Alameda County because the conduct and events giving rise to the claims at issue occurred in Alameda County. The Plaintiffs reside in this county, the purchase and injuries occurred in the county, and relevant evidence and witnesses are believed to be located in the county.

[3] Global Pharma Healthcare, Our Presence, accessed Feb. 16, 2023, https://global-pharma.com/ourpresence.html.

Plaintiffs expressly disclaim that any of their causes of action rely upon federal law and/or present a federal question.

FACTS OF THE CASE

Through the Christmas of 2022, Plaintiff Milton Reynolds was battling an eye infection so severe that he feared doctors would have to remove his right eye. The infection melted his cornea, causing him to endure, among other things, emergency room visits, two surgeries, and regular intravitreal injections (shots in his eye). Ultimately, Mr. Reynolds went blind in his right eye.

In January 2023, Mr. Reynolds received a call from the Alameda County Office of Public Health, inquiring about Mr. Reynolds' injuries and whether he had purchased EzriCare Artificial Tears. That was when he learned that his suffering and blindness was caused because of simple, lubricating eye drops that he bought on Amazon.

The Outbreak – Pseudomonas Aeruginosa

On January 20, 2023, the US Center for Disease Control and Prevention ("CDC") spotted an outbreak of a rare bacterial infection in 11 (now 12) different states, including California.[4] At the time, the infections were known to have affected 55 people between May and December of 2022.[5] Some of the people infected suffered permanent vision loss, and one person even died when the infection entered his bloodstream.[6]

The CDC searched for a cause of the outbreak and found one: "Recent epidemiology and laboratory evidence link these infections to use of EzriCare Artificial Tears."[7] The CDC obtained bacterial samples from the people infected and reported that it found a strain of bacteria that has never been reported in the United States, called Verona Integron-mediated Metallo-β-lactamase and Guiana-Extended Spectrum-β-Lactamase producing carbapenem-resistant *Pseudomonas aeruginosa*

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[4] Center for Disease Control and Prevention ("CDC"), Update: Multistate Cluster of VIM- and GES-producing Carbapenemresistant *Pseudomonas aeruginosa* associated with Artificial Tears, Jan. 20, 2023, https://www.aao.org/Assets/3a187c94-7889-42e8-84a1-6b2e88e7d374/638098403609770000/epix-multistate-pseudomonas-investigation-20jan2023-pdf?inline=1. The states affected were CA, CO, CT, FL, NJ, NM, NY, NV, TX, UT, WA, and WI.

[5] *Id.*

[6] *Id.*

[7] *Id.*

("VIM-GES-CRPA").[8] The CDC then compared that strain of bacteria to the bacteria collected from opened bottles of EzriCare Artificial Tears – they were the same bacteria.[9] Testing of unopened bottles of EzriCare Artificial Tears is ongoing.[10]

Both the CDC and the Food and Drug Administration ("FDA") have advised citizens to stop using Artificial Tears, because the strain of *Pseudomonas aeruginosa* bacteria that they found in the outbreak is a danger to humans. For example, scientists have known for decades that, when *Pseudomonas aeruginosa* is introduced into the eye, "as . . . in contaminated medicines, it acts with **extreme virulence**, in many cases causing blindness and even necessitating enucleation." [11] "Enucleation" means surgical removal of the entire eyeball.

The strain of *Pseudomonas aeruginosa* found in the outbreak is reported to be "extensively drug-resistant," making it especially difficult for doctors to treat.[12] The strain appears to resist cefepime, ceftazidime, piperacillin-tazobactam, aztreonam, carbapenems, ceftazidime-avibactam, ceftolozane-tazobactam, fluoroquinolones, polymyxins, amikacin, gentamicin, and tobramycin.[13]

The Aftermath of the Outbreak

Four days after the CDC issued its public statement specifically linking the potentially-deadly *Pseudomonas aeruginosa* to EzriCare, EzriCare reported on its website that the CDC was merely investigating "adverse events" related to "various" over the counter eye drops. Moreover, although infections had been under investigation by the CDC for approximately nine months, EzriCare disclaimed that it had received *any* consumer complaints or adverse event reports, and the company reported that it had not been asked to recall Artificial Tears.[14]

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[8] CDC, Outbreak of Extensively Drug-resistant *Pseudomonas aeruginosa* Associated with Artificial Tears, Feb. 1, 2023, https://emergency.cdc.gov/han/2023/han00485.asp.

[9] *Id.*

[10] *Id.*

[11] William H. Spencer, *Pseudomonas Aeruginosa Infections of the Eye*, Calif Med. 1953 Dec; Vol. 79(6) at 438–443., https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1521875/ (emphasis added).

[12] CDC, Outbreak of Extensively Drug-resistant *Pseudomonas aeruginosa* Associated with Artificial Tears, Feb. 7, 2023, https://www.cdc.gov/hai/outbreaks/crpa-artificial-tears.html.

[13] *Id.*

[14] EzriCare, EzriCare Artificial Tears - Discontinue Use, Jan. 24 – Feb. 2, 2023, https://ezricare-info.com/

Several days after that, on February 1, 2023, EzriCare issued a statement all but blaming the bacterial contamination of Artificial Tears on its manufacturer, Global Pharma Healthcare, and/or its distributor, Aru Pharma:

> The EzriCare Artificial Tears product is manufactured in India by Global Pharma Healthcare PVT Limited and imported into the United States by Aru Pharma Inc. . . . EzriCare, LLC had no role in the formulation, packaging delivery system design or actual manufacturing of this product.[15]

Though, in that same statement, EzriCare did specifically own that it is responsible for the labeling and marketing of Artificial Tears: "EzriCare, LLC's only role in introducing the product to the market was to design an exterior label and to market it to our customers."[16]

On February 2, 2023, Global Pharma Healthcare issued a nationwide recall of Artificial Tears distributed by EzriCare "due to possible contamination."[17] The recall's risk statement specifically acknowledges that "[u]se of contaminated artificial tears can result in the risk of eye infections that could result in blindness."[18]

On February 3, 2023, the FDA placed Global Pharma Healthcare on import alert, preventing Artificial Tears from entering the country, finding evidence that Artificial Tears appeared to be in violation of U.S. laws and regulations.[19] The FDA cited Global Pharma Healthcare for "not complying with [Current Good Manufacturing Practice] requirements," as well for providing an inadequate response to FDA records requests. [20]

Artificial Tears & Violations of California Law

California law forbids violations of Current Good Manufacturing Practice ("CGMP") requirements. Through the state's Sherman Food Drug and Cosmetics Laws ("Sherman Laws"), California has adopted as its own law all nonprescription drug regulations and good manufacturing

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[15] *Id.*
[16] *Id.*
[17] Global Pharma Healthcare, Global Pharma Healthcare Issues Voluntary Nationwide Recall of Artificial Tears Lubricant Eye Drops Due to Possible Contamination, Feb. 2, 2023, http://www.global-pharma.com/otc.pdf.
[1818] *Id.*
[19] Food and Drug Administration, FDA Warns Consumers Not to Purchase or Use EzriCare Artificial Tears Due to Potential Contamination, Feb. 2, 2023, https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-ezricare-artificial-tears-due-potential-contamination.
[20] *Id.*

practices found in the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 *et seq*, 21 C.F.R. 820 *et seq.*). E.g. Cal. Health & Safety Code §§ 110111, 110105. Thus, California law requires sanitary conditions at the manufacturing facility (including packaging or similar facilities) and testing to ensure that eye drops will be sterile and safe when used by the consumer.

Among CGMP violations that the FDA cited were (1) lack of appropriate microbial testing and (2) a formulation issue (the fact that the company packages the eye drops in multi-use bottles without a preservative). Although investigation currently remains ongoing, these are the ways that the bacteria *Pseudomonas aeruginosa* came to contaminate Artificial Tears.

First, on information and belief, because of unsanitary conditions, the lack of appropriate microbial testing, and the lack of adequate documentation and pharmacovigilance, *Pseudomonas aeruginosa* contaminated Artificial Tears at the time of manufacturing or packaging. The CDC's investigation remains ongoing.

Global Pharma knows the danger presented by unsanitary conditions and the lack of microbial testing. Its website touts that its "manufacturing process is studied and perfected by a quality control department in order to ensure that Global Pharma formulations are of the highest quality."[21] "Our team of dedicated professionals, with the help of computer controlled test equipment, scrutinize each product as it goes through a series of checkpoints."[22] "A separate quality assurance team monitors the entire process of production. Our laboratory is equipped with the latest equipment . . . . It is well equipped to perform all necessary chemical and microbiological assays."[23] "We at Global Pharma are committed to ensure our products are of the highest quality and pharmacovigilance is an essential part of this. Our ongoing processes allow for feedback to be received and acted upon in a timely and efficient manner."[24] More specifically, Global Pharma touts that its manufacturing facility "has been meticulously designed for the manufacturing of . . . sterile eye drops . . . . It has been audited by the Ministries of Health of over 12 countries . . . ."[25]

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[21] Global Pharma Healthcare, Quality and Pharmacovigilance, visited Feb. 21, 2023, http://www.global-pharma.com/quality.html.

[22] *Id.*

[23] *Id.*

[24][24] *Id.*

[25] Global Pharma Healthcare, Manufacturing, visited Feb. 21, 2023, https://global-pharma.com/manufacturing.html.

Similarly, EzriCare's website touts itself as a "forward-thinking 21st century, Generic OTC Drug Company" whose "products have the same high quality active ingredients as most leading brands."[26] "We pride ourselves on providing our customers the biggest bang for their buck while also ensuring they remain highly satisfied in . . . our product quality . . . ."[27]

The dangers of unsanitary conditions and the need for testing, pharmacovigilance, and company oversight of drug manufacturing facilities in India has long been known to industry members like Defendants. For example, a 2015 article in the Financial Times, titled *Indian Drugs: Not What the Doctor Ordered* reported that, in 2015 alone, six Indian manufacturers were blacklisted by the FDA and that 39 drug-manufacturing facilities – owned by 27 different companies – lost their clearance to make drugs for U.S. markets because of regulatory problems.[28] Such "regulatory problems" have very real and very steep consequences: for example, in October of last year, contaminated, Indian-made cough syrup killed 70 children in West Africa.[29] This is not a one-time problem; activists say there is a "longstanding laxness in regulating India's booming pharmaceutical industry."[30]

Thankfully, companies that deal in pharmaceuticals sold in America are held to a higher standard. California law recognizes, for example, that "[i]nformed medical opinion is in agreement that all preparations offered or intended for ophthalmic use . . . should be sterile." *Id.* (incorporating 21 C.F.R Parts 200.50, 211). "It is further evident that such preparations purport to be of such purity and quality as to be suitable for safe use in the eye." *Id.* "[A]ll such preparations, if they are not sterile, fall below their professed standard of purity or quality and may be unsafe." *Id.* Testing is likewise required to ensure safety. *Id.*

Alternatively, on information and belief, because of a formulation issue – namely, that Artificial Tears was placed in *multi-use* bottles and without a preservative to kill bacteria –

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[26] EzriCare, About Us, visited Feb. 21, 2023, https://ezricare.com/pages/about-us.
[27] *Id.*
[28] Financial Times, *Indian Drugs: Not What the Doctor Ordered*, Sep. 2015, https://www.ft.com/content/de0ca3f4-5581-11e5-97e9-7f0bf5e7177b
[29] NPR, *Contaminated Cough Syrup from India Linked to 70 Child Deaths. It's Happened Before.*, Oct. 2022, https://www.npr.org/sections/goatsandsoda/2022/10/18/1128530220/contaminated-cough-syrup-from-india-linked-to-70-child-deaths-its-happened-befor.
[30] *Id.*

Pseudomonas aeruginosa foreseeably contaminated the bottles of Artificial Tears after they were opened, even though they were used as directed. Medical professionals have long warned that placing a preservative-free eyedrop inside a multi-use eyedrop bottle is dangerous, precisely because there is no preservative to kill bacteria; even seemingly benign and foreseeable acts – like brushing an eyelash while applying the drops – can cause harmful contamination of the multi-use bottle when it lacks a preservative. When no preservative is added to eye drops, the drops must be packaged more safely, for example, in single-use vials or specially-designed multi-use bottles (that prevent drops and air from reentering and contaminating the bottle).

California's Sherman Laws require that EzriCare's eye drops be packaged more safely. If eye drops are sold in a multi-dose container, like EzriCare's, they must either contain a substance to inhibit the growth of microorganisms *or* "be so packaged as to volume and type of container and so labeled as to duration of use and with such necessary warnings to afford adequate protection and minimize the hazard of injury resulting from contamination during use." Cal. Health & Safety Code §§ 110111, 110105 (incorporating 21 C.F.R. 200.50(b)). To this end, notably, the brand-name eye drops, Refresh Plus (for which EzriCare is the generic), are sold in *single-use* vials, pictured below – *not* a multidose bottle, like Artificial Tears.

Especially given the manufacturing and formulation issues inherent in Artificial Tears, EzriCare's warning label was particularly weak. It warned not to use the product if the solution changed color or became cloudy; to see a doctor if the user experienced eye pain, changes in

vision, or redness/irritation; and it stated that contamination *could be avoided* by not touching the tip of the container to any surface, replacing the cap, and removing contact lenses before using. The label did not warn, for example, because the product is preservative-free and irresponsibly packaged it is more susceptible to contamination and more likely to cause serious, life-altering infections.

Plaintiffs Milton Reynolds & Danae Reynolds

Like many Americans, Plaintiff Milton Reynolds gets dry eyes when he works on a computer. He decided to purchase some lubricating eye drops. Sadly, that seemingly-innocuous decision would change his life.

On June 24, 2022, Mr. Reynolds purchased two bottles of EzriCare Artificial Tears from Amazon. He used the Artificial Tears dozens of times. Then, his right eye inexplicably began to tear up, and he began experiencing eye pain.

In October 2022, Mr. Reynolds visited his ophthalmologist for treatment of his symptoms. His ophthalmologist sent him to the emergency room. Mr. Reynolds was experiencing "cornea melt" – an infection was eating his cornea.

Through Thanksgiving 2022, Mr. Reynolds continued receiving critical medical treatment for his eye, including (but not limited to) shots in his right eye and emergency room visits. On two occasions, doctors glued his right eyeball together to keep the eye from imploding from the infection. Mr. Reynolds compared the physical pain caused by the infection to knives sticking into his head. The doctors advised Mr. Reynolds that they may need to remove his infected eyeball.

On the day after Thanksgiving, Mr. Reynolds underwent surgery for a full cornea replacement. Around that time, Mr. Reynolds' doctors confirmed that Mr. Reynolds was suffering from a rare strain of *Pseudomonas aeruginosa*.

However, Mr. Reynolds' suffering was not over: He endured a second surgery to clear the back of his eye. His injuries continued to force him into the emergency room. And Mr. Reynolds continued to visit his doctors frequently for critical treatment, including more shots in his eye.

Mr. Reynolds has lost sight in his right eye. He continues to see doctors. Mrs. Reynolds, his wife, must both see her husband suffer and participate in his care and treatment, which is

emotionally and physically taxing and puts a strain on the relationship. Ms. Reynolds can no longer sleep in the same bed with Mr. Reynolds for fear of exacerbating his injury. The Reynolds have been negatively impacted by loss of companionship, comfort, care, assistance, protection, affection (both physical and emotional), society, and moral support. Mr. Reynolds has experienced severe pain and suffering, both physical and emotional, and he will continue to require treatment in the future.

CAUSES OF ACTION

Count I

Strict Liability – Manufacturing Defect

Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth here in their entirety.

Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers, marketers, advertisers, and/or sellers of the product Artificial Tears. Each Defendant received direct financial benefit from its activities and the sale of the product at issue. Each Defendant was integral to the business enterprise such that Defendants' conduct was a necessary factor in bringing the product to the customer market. Each Defendant had control over or a substantial ability to influence the distribution and marketing process.

The product was defective in that it was contaminated with *Pseudomonas aeruginosa*. Because it was contaminated, it differed from the manufacturer's design or specifications or from other typical units of the same product line. The product was defective when it left Defendants' possession. Mr. Reynolds used Artificial Tears in a reasonably foreseeable manner. He suffered harm, and the defect in the product was a substantial factor in causing that harm.

On information and belief, Defendants acted with malice, oppression, or fraud – including, but not limited to, acting with willful and knowing disregard for the rights or safety of others, for example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the probable dangerous consequences of their conduct and deliberately failed to avoid those consequences.

Count II

Strict Liability – Design Defect

Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth here in their entirety.

Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers, marketers, advertisers, and/or sellers of the product Artificial Tears. Each Defendant received direct financial benefit from its activities and the sale of the product at issue. Each Defendant was integral to the business enterprise such that Defendants' conduct was a necessary factor in bringing the product to the customer market. Each Defendant had control over or a substantial ability to influence the distribution and marketing process.

The product's design was defective because it enabled the product to be contaminated with *Pseudomonas aeruginosa* and, thus, did not perform as safely as an ordinary consumer would have expected it to perform when used or misused in an intended or reasonably foreseeable way. Alternatively, the design was defective because it enabled the product to be contaminated with *Pseudomonas aeruginosa* and the risks associated with the product's design outweighed its benefits. Mr. Reynolds was harmed. The product's design or failure to perform safely was a substantial factor in causing the harm suffered by Mr. Reynolds.

On information and belief, Defendants acted with malice, oppression, or fraud – including, but not limited to, acting with willful and knowing disregard for the rights or safety of others, for example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the probable dangerous consequences of their conduct and deliberately failed to avoid those consequences.

Count III

Strict Liability – Failure to Warn

Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth here in their entirety.

Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers, marketers, advertisers, and/or sellers of the product Artificial Tears. Each Defendant received direct

financial benefit from its activities and the sale of the product at issue. Each Defendant was integral to the business enterprise such that Defendants' conduct was a necessary factor in bringing the product to the customer market. Each Defendant had control over or a substantial ability to influence the distribution and marketing process.

The product had potential risks, side effects, or adverse reactions that were known or knowable in light of the scientific and/or medical knowledge at the time of the product's manufacture, distribution, packaging, labeling, supplying, marketing, advertising, and/or selling – for example, that it may be contaminated with a potentially-deadly bacteria. The potential risks, side effects, and/or adverse reactions presented a substantial danger when the product was used or misused in an intended or reasonably foreseeable way. Ordinary consumers would not have recognized the potential risks, side effects, or adverse reactions. Defendants had a duty to warn and to continually update warnings. Defendants failed to adequately warn or instruct or update the potential risks, side effects, or adverse reactions. Mr. Reynolds was harmed. The lack of sufficient instructions or warnings was a substantial factor in causing the harm that Mr. Reynolds suffered.

On information and belief, Defendants acted with malice, oppression, or fraud – including, but not limited to, acting with willful and knowing disregard for the rights or safety of others, for example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the probable dangerous consequences of their conduct and deliberately failed to avoid those consequences.

Count IV

Negligence & Gross Negligence

Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth here in their entirety.

Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers, marketers, advertisers, and/or sellers of the product Artificial Tears. As such, Defendants owed Plaintiff a duty of care and a duty to assist and protect, including but not limited to a duty of reasonable care to manufacture, test, design, distribute, package, label, supply, market, advertise, and/or sell a product that was not unreasonably safe for human use. The product was either inherently

dangerous or reasonably certain, if negligently manufactured, designed, distributed, packaged, labeled, supplied, marketed, advertised, and/or sold to place life and limb in peril. It was or became contaminated with *Pseudomonas aeruginosa.* Defendants were negligent in manufacturing, designing, distributing, packaging, labeling, supplying, marketing, advertising, and/or selling the product. Defendants failed to use the amount of care in manufacturing, distributing, packaging, labeling, supplying, marketing, advertising, and/or selling the product that a reasonably careful manufacturers, designers, distributors, packagers, labelers, suppliers, marketers, advertisers, and/or sellers would use in similar circumstances to avoid exposing others to a foreseeable risk of harm. Alternatively, Defendants failed to use any care or made an extreme departure from what a reasonably careful person would do in the same situation to prevent harm to oneself or to others. Mr. Reynolds was harmed, and Defendants' negligence was a substantial factor in causing that harm.

On information and belief, Defendants acted with malice, oppression, or fraud – including, but not limited to, acting with willful and knowing disregard for the rights or safety of others, for example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the probable dangerous consequences of their conduct and deliberately failed to avoid those consequences.

Count V

Negligent Failure to Warn

Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth here in their entirety.

Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers, marketers, advertisers, and/or sellers of the product Artificial Tears. As such, Defendants owed Plaintiff a duty of care and a duty to assist and protect, including but not limited to a duty of reasonable care to manufacture, test, design, distribute, package, label, supply, market, advertise, and/or sell a product that was not unreasonably safe for human use.

Defendants had a duty to properly supervise, train, and monitor its agents, subcontractors, and employees who prepared the product to ensure compliance with Defendants' operating standards and

to ensure compliance with all applicable regulations. Defendants failed to properly supervise, train, and monitor these agents, subcontractors, and employees and thus breached that duty.

Defendants owed a duty to Plaintiff to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, testing, distribution, storage, labeling, and sale of its products, including all applicable local, state, and federal health and safety regulations – as incorporated into California law. Defendants failed to conform to this duty.

Defendants knew or reasonably should have known that the product was dangerous or was likely to be dangerous when used or misused in a reasonably foreseeable manner. The product was or became contaminated with *Pseudomonas aeruginosa.* Defendants knew or reasonably should have known that users would not realize the danger. Defendants failed to adequately warn of the danger or instruct on the safe use of the product. A reasonable manufacturer, designer, distributor, packager, labeler, supplier, marketer, advertiser, and/or seller under the same or similar circumstances would have warned of the danger or instructed on the safe use of the product.

Alternatively, Defendants failed to use any care or made an extreme departure from what a reasonably careful person would do in the same situation to prevent harm to oneself or to others.

Mr. Reynolds was harmed. Defendants' negligent failure to warn or instruct was a substantial factor in causing the harm suffered by Mr. Reynolds.

On information and belief, Defendants acted with malice, oppression, or fraud – including, but not limited to, acting with willful and knowing disregard for the rights or safety of others, for example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the probable dangerous consequences of their conduct and deliberately failed to avoid those consequences.

Count VI

Negligent Failure to Recall

Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth here in their entirety.

Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers, marketers, advertisers, and/or sellers of the product Artificial Tears. As such, Defendants owed

Plaintiff a duty of care and a duty to assist and protect, including but not limited to a duty of reasonable care to manufacture, test, design, distribute, package, label, supply, market, advertise, and/or sell a product that was not unreasonably safe for human use.

Defendants knew or reasonably should have known that the product was dangerous or was likely to be dangerous when used in a reasonably foreseeable manner. It was or became contaminated with *Pseudomonas aeruginosa*. Defendants became aware of this defect after the product was sold. Defendants failed to recall or warn of the danger of the product. A reasonable manufacturer, designer, distributor, packager, labeler, supplier, marketer, advertiser, and/or seller under the same or similar circumstances would have recalled the product. Alternatively, Defendants failed to use any care or made an extreme departure from what a reasonably careful person would do in the same situation to prevent harm to oneself or to others. Mr. Reynolds was harmed. Defendants' failure to recall the product was a substantial factor in causing the harm suffered by Mr. Reynolds.

On information and belief, Defendants acted with malice, oppression, or fraud – including, but not limited to, acting with willful and knowing disregard for the rights or safety of others, for example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the probable dangerous consequences of their conduct and deliberately failed to avoid those consequences.

Count VII

Negligence Per Se

Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth here in their entirety.

Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers, marketers, advertisers, and/or sellers of the product Artificial Tears. Defendants were required to follow the laws set forth in California's Sherman Food Drug and Cosmetics Laws. Such laws require, for example, sanitary conditions at the manufacturing facility so that eye drops will be sterile and safe. Cal. Health & Safety Code §§ 110111, 110105 (incorporating 21 U.S.C. Sec. 301 *et seq.* and regulations, including but not limited to 21 C.F.R Parts 200.50, 211 and 21 C.F.R. 820 *et seq.*). Defendants violated the laws. Mr. Reynolds suffered harm. Mr. Reynolds was in the class of

persons intended to be protected by the laws that Defendants failed to follow. Defendants' violations of the law were a substantial factor in bringing about the harm that Mr. Reynolds suffered.

Plaintiff expressly disclaims that this – or any – of its causes of action are brough pursuant to federal law. Plaintiff's claims are based on California law.

On information and belief, Defendants acted with malice, oppression, or fraud – including, but not limited to, acting with willful and knowing disregard for the rights or safety of others, for example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the probable dangerous consequences of their conduct and deliberately failed to avoid those consequences.

Count VIII

Breach of Express Warranty

Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth here in their entirety.

Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers, marketers, advertisers, and/or sellers of the product Artificial Tears. Defendants warranted to Mr. Reynolds that the product was safe, effective, comparable to Refresh Plus Eye Drops, not adulterated with harmful bacteria, could be used so that it would not become adulterated with harmful bacteria, was prepared under sanitary conditions, and sterile. The product did not perform as promised; it was or became contaminated with bacteria, and it was not comparable to Refresh Plus Eye Drops. Defendants failed to make the product safe and effective. Mr. Reynolds was harmed. The failure of the product to be as represented was a substantial factor in causing the harm that Mr. Reynolds suffered.

On information and belief, Defendants acted with malice, oppression, or fraud – including, but not limited to, acting with willful and knowing disregard for the rights or safety of others, for example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the probable dangerous consequences of their conduct and deliberately failed to avoid those consequences.

Count IX

Breach of Implied Warranty

[Common Law & CUCC § 1794(a)]

Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth here in their entirety.

Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers, marketers, advertisers, and/or sellers of the product Artificial Tears. Mr. Reynolds bought the product from Defendants. At the time of the purchase, Defendants were in the business of manufacturing, designing, distributing, packaging, labeling, supplying, marketing, advertising, and/or selling the product or held themselves out as having special knowledge or skill regarding these goods. Defendants warranted that the product was safe, effective, comparable to Refresh Plus Eye Drops, not adulterated with harmful bacteria, could be used so that it would not become adulterated with harmful bacteria, was prepared under sanitary conditions, and sterile. Instead, the product was or became contaminated with harmful bacteria. Thus, the product was not of the same quality as those generally acceptable in the trade; was not fit for the ordinary purposes for which such goods are used; was not adequately contained, packaged, or labeled; and did not measure up to the promises or facts stated on the container or label. Mr. Reynolds was harmed. The failure of the product to have the expected quality was a substantial factor in causing Mr. Reynold's harm.

Alternatively, at the time of purchase, Defendants knew or had reason to know that Mr. Reynolds intended to use the product for a particular purpose and knew or had reason to know that Mr. Reynolds was relying on their skill and judgment to select or furnish a product that was suitable for the particular purpose. Mr. Reynolds justifiably relied on Defendants' skill and judgment. The product was not suitable for the particular purpose because it was or became contaminated with bacteria. Mr. Reynolds was harmed. The failure of the product to be suitable was a substantial factor in causing the harm suffered by Mr. Reynolds.

On information and belief, Defendants acted with malice, oppression, or fraud – including, but not limited to, acting with willful and knowing disregard for the rights or safety of others, for example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the

probable dangerous consequences of their conduct and deliberately failed to avoid those consequences.

Count X

Fraud

Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth here in their entirety.

Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers, marketers, advertisers, and/or sellers of the product Artificial Tears. Defendants represented that the product was safe, effective, comparable to Refresh Plus Eye Drops, not adulterated with harmful bacteria, could be used so that it would not become adulterated with harmful bacteria, was prepared under sanitary conditions, and sterile. Instead, the product was or became contaminated with harmful bacteria – or concealed information regarding the same. As such, Defendants' representation was false. Defendants knew that the representation was false when they made it, or they made the representation recklessly and without regard for its truth. Alternatively, though Defendants may have honestly believed that the representation was true, Defendants had no reasonable grounds for believing the representation was true when they made it. Defendants intended for Mr. Reynolds to rely on the representation, and he did reasonably rely on the representation. Mr. Reynolds was harmed. His reliance on Defendants' representation was a substantial factor in causing his harm.

On information and belief, Defendants acted with malice, oppression, or fraud – including, but not limited to, acting with willful and knowing disregard for the rights or safety of others, for example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the probable dangerous consequences of their conduct and deliberately failed to avoid those consequences.

Count XI

Loss of Consortium

Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth here in their entirety.

Mr. and Mrs. Reynolds are married and were married at all times relevant to this lawsuit. Ms. Reynolds was harmed by the injury that Mr. Reynolds suffered because he used Artificial Tears, as alleged herein. Ms. Reynolds suffered loss of love, companionship, comfort, care, assistance, protection, affection (both physical and emotional), society, and moral support. For example, the injuries have caused Mrs. Reynolds spend more time caretaking, thus putting undue strain on the marital relationship. Seeing her husband suffer is emotionally taxing. Further, because of Mr. Reynolds' injuries, they can no longer even sleep in the same bed for fear of exacerbating the injuries. This loss of consortium was proximately caused by the injury that Mr. Reynolds suffered when he used Artificial Tears.

DAMAGES

Mr. and Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth here in their entirety. Defendants' conduct was a direct, proximate, and producing cause of Plaintiff's injuries and damages, including but not limited to damages in the past and future, including but not limited to: pain and suffering, mental anguish, emotional distress, physical impairment, physical disfigurement, loss of enjoyment of life, medical and pharmaceutical expenses, travel and travel-related expenses, emotional distress, lost wages, lost earning capacity, punitive and/or exemplary damages and attorneys' fees (to the extent recoverable) and other general, special, ordinary, incidental and consequential damages as would be anticipated to arise under the circumstances. On information and belief, Defendants acted with malice, oppression, or fraud – including, but not limited to, acting with willful and knowing disregard for the rights or safety of others, for example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the probable dangerous consequences of their conduct and deliberately failed to avoid those consequences.

PRAYER FOR RELIEF

WHEREFORE Plaintiffs pray for the following:

1. Past and future economic and non-economic damages, general and specific damages, in an amount to be determined at trial;
2. Punitive damages;
3. Such other sums as shall be determined to fully and fairly compensate Plaintiffs for all general, special, incidental, and consequential damages incurred or to be incurred as the direct and proximate result of the acts and omissions of Defendants;
4. Costs, disbursements, and reasonable attorneys' fees to the extent allowed by law;
5. Pre- and post-judgment interest at the highest rate allowed by law;
6. That the Court award such other and further relief as it deems necessary and proper in the circumstances; and
7. That the Court award Plaintiffs the opportunity to amend or modify the provisions of this Complaint as necessary or appropriate after additional or further discovery is completed in this matter, and after all appropriate parties have been served.

JURY TRIAL DEMAND

Plaintiffs demand a jury trial on all of the issues raised in this Complaint.

Dated: February 22, 2023

Respectfully submitted,

THE LANIER LAW FIRM

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